

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 09/740,679 Confirmation No.: 6074
Applicant : J. Stuart Cumming
Filing Date : 12/19/2000
Title : ACCOMMODATING INTRAOCULAR LENS
Group Art Unit : 3732
Examiner : Paul B. Prebilic
Docket No. : 13533.4033
Customer No. : 34313

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF ARTHUR ASTORINO, JR. M.D.

Sir:

Arthur Astorino, Jr. graduated Summa Cum Laude with distinction from the Department of Biomedical Engineering at Duke University in 1979. He received his M.D. degree at Baylor College of Medicine in 1983, completed his internship at St. Joseph Hospital in Houston, Texas in 1984, and his Ophthalmology residency at the Jules Stein Eye Institute, UCLA Medical Center from 1985-1988.

After several years of experience as a cataract diagnostician and surgeon, Dr. Astorino formed the Astorino & Associates Eye Center in Newport Beach, California in 1993. Astorino & Associates provides comprehensive care, including Lasik and Cataract surgery, implantation of intraocular lenses and Crystalens® accommodating intraocular lenses and treatment of conditions including Glaucoma, retinal diseases and diabetes, macular degeneration, and thyroid eye disease.

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Dr. Astorino is certified by the American Board of Ophthalmology (ABO), is a fellow of the American Society of Cataract and Refractive Surgery (ASCRS) and is an Assistant Professor of Clinical Ophthalmology at UCLA. He retains staff privileges at Hoag Hospital in Newport Beach, California. He is a member of several professional organizations, and has served on the Board of the Association of American Physicians and Surgeons (AAPS).

* * *

I, Dr. Astorino, have reviewed the above-identified patent application and claims, the Examiner's comments in the Examiner's Office Action dated July 19, 2007, and have reviewed in detail the patents cited by the Examiner, and principally Schlegel No. 4,424,597.

As an ophthalmologist who has practiced for many years, I am very familiar with accommodating lenses of the type disclosed in the present application. It is my opinion that the Schlegal lens optic was not designed to move back and forth axially to any extent to provide accommodation and because of the design shown and described in his patent would not move in this direction to produce accommodation.

Many lenses of the type shown, described and claimed (including the claims of the present preliminary amendment) have been implanted by me.

The Schlegal lens design is not one with haptics as in the present application. In my opinion, the circular structure of the Schlegal supports would not allow a forward bend during ciliary muscle contraction as the lens of the present application does. There is no design suggested by Schlegal to allow this to happen. Contraction forces inward by the ciliary muscle would not be channeled in any specific direction, and would be radially directed and would tend to cancel out. Within the section "Summary of the Invention," Schlegal brings about many points that show that his

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intention was to produce a stable lens as opposed to a flexible lens and by no means intended for his lens to move with respect to ciliary muscle movement. Schlegel states "The Lens to be made should have as great a mechanical stability as possible" (column 2, lines 27-29). This is opposed to having a lens designed to react to strain forces produced by ciliary muscle contraction to produce accommodation. His intent was to produce a lens that had no strain nor interaction with surrounding tissue. He states "The Lens . . . gives rise to a very, very slight mechanical tissue strain on the surrounding tissue, if at all." (column 2, lines 32-35). He further states "It is a further object of the invention that the lens should be free from any inner-mechanical stresses." (column 2, lines 42-43). It could not be made more clearly that Schlegel designed his lens for stability without any intention for movement in reaction to forces generated during ciliary muscle movement.

With regard to the several openings in the support element of Schlegel, to assume they are to provide flexibility to allow for accommodating is clearly reading something into the design that is not there. In addition, there is no representation in the Schlegel patent to provide a specific placement of the holes to give a precise change in flexibility so that the lens and support could somehow act as a hinge. On the other hand, the lens designs in the present application provide very specific designs which are intended to take advantage of the forces created in the eye during accommodation to move the lens forward and backward. Schlegel's patent has a complete lack of any teaching or suggestion of a linear groove or other area across each haptic adjacent and tangential to the optic to allow axial movement of the optic with respect to the outer ends of the haptics as is the case with lenses of the present application.

Further, with respect to the holes, note column 4, lines 9-14, ". . . having the task of letting aqueous humor pass through." Again, he does not suggest nor state that the holes are placed to produce flexibility. Providing a pathway for aqueous to

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flow through the lens is the opposite of what one would want to do if Schlegal was aware of wanting to produce forward movement of the lens in response to ciliary muscle contraction as is the purpose of the designs in the present application. If so, Schlegal would not want holes in the lens because that might relieve the pressure build-up behind the lens from accommodative effort that helps move the lens forward as with lenses of the present application. As further evidenced that Schlegal wanted a stable instead of a flexible lens design, he states that “. . . reinforcement ribs 16 can be arranged on the support ring 12, which simultaneously serve to keep off adjacent tissue from the surface of the support ring 12, in particular in the area of the holes 15.” (column 4, lines 10-14).

The cross-direction of bending described by Schlegal is the opposite direction to the bending of a lens of the present application for achieving accommodation.

Schlegal also describes a bend backward in one design, Fig. 4 (column 4, lines 57-68). It is important to note that this bend is not a hinge nor in any way designed to create or allow movement of the lens forward and backward with ciliary muscle movement. The purpose of the bend for Schlegal is to “. . . enable the rear surface 13 of the lens body 11 coming to rest further in, i.e., towards the center point of the eyeball . . .” (column 4, lines 60-62). He does this because he wants to create a posterior curvature that he can keep constant for all implants and adjust the power of the IOL by adjusting the power and curvature of the front surface. This is not done to create an accommodation lens.

The Examiner's Comment - Page 5 *“Schlegal anticipates that claim language where the lens and haptic structure is made entirely out of flexible silicone and it is inherently capable of accommodating due to flexing at the haptics to the extent required by the claim language...”*

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I disagree with this comment. First of all the comment “inherently capable of accommodating” simply because it is made out of silicone is not true. There is nothing in the patent that discusses the inherent property of silicone as being “flexible” allowing accommodation. As indicated in the analysis above on Schlegel’s patent, he is concerned with creating a stable lens to hold back the vitreous and create a wall separating the anterior and posterior chambers.

The reason for Figures 3 and 4 is to show a lens that supports the posterior capsule bag and has a steep posterior curvature. He intends that his lens is stable and provides support not with flexibility. The only time he discusses bending of the lens is in the “cross” direction to help with inserting the lens into the eye and presumably through the incision.

Examiner’s Comment - Page 5. *“Furthermore, the holes are added to the haptics to make them even more flexible as desired...”*

As I showed in my analysis of Schlegel above, Schlegel is not providing the holes for flexibility, in fact he never mentions flexibility, he is primarily providing them for aqueous flow, fibrosis and he mentions that they may allow for bending in the “cross” direction which will aid in implantation into the eye. No where is the “cross direction” defined unambiguously and as per the examples.

As I stated above, I believe that the cross direction indicates that the lens could bend along its long axis so that it could make its thinner diameter even smaller to fit through the incision more readily than a PMMA lens of similar size. To take this statement, and suggest that it is an obvious conclusion from the Schlegel patent that this lens design is capable of moving forward and backward in the anterior and posterior direction with accommodative effort can only be entertained after a discovery like that made by Dr Cumming with his design of the crystalens.

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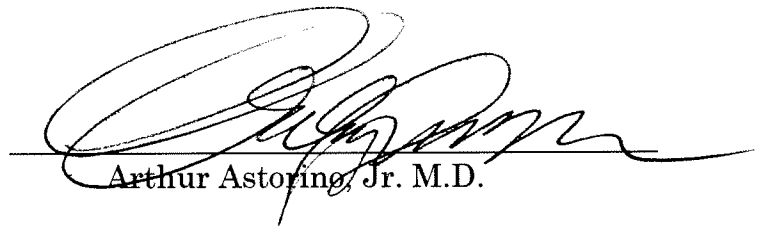
In fact even in the cited patent by Wiley, column 2, lines 39 to 41, dated 1991 (10 years after Schlegel) he states "...ophthalmologists have never been able to correct for accommodation of vision from a distance to near vision..." Apparently 10 years after Schlegel it was not obvious that a haptic configuration made of silicone as per Schlegel is "inherently capable" of providing accommodation.

In summary, that which constitutes the invention of Dr Cumming is being denied based on prior art that was not created to produce accommodation and the properties of the prior art are designed specifically to provide functionality unrelated to accommodation.

The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any resulting patent, declares that the facts set forth above are true; all statements made of his own knowledge are true; and all statements made on information and belief are believed to be true.

Dated:

12/27/07


Arthur Astorino, Jr. M.D.